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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,991	01/23/2002	Hirofumi Yura	33944	8819

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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 04/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/937,991	Applicant(s) YURA ET AL.	
	Examiner Ganapathy Krishnan	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

The amendment filed December 24, 2003 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. New claims 11 and 12 have been added.
2. Remarks drawn to rejections under 35 USC 102.

Claims 1-3 and 6-12 are pending in the case.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Specification

The objection to the specification has been overcome by amendment.

Claim Rejections - 35 USC § 102

Claims 1-3 and 6-11 rejected under 25 U.S.C. 102(b) as being anticipated by Tay et al (Biomaterials, 1989, vol. 10(1), pp 1-15) and Larsson et al (WO 93/05793) is being maintained for reasons of record. Tay teaches the limitations of instant claims 1-3, 6-11 and Larsson teaches the limitations of instant claims 1-3 and 6-10.

Applicants arguments have been considered but not found to be persuasive.

Applicants argue that Tay does not disclose a carbohydrate chain W in each monomeric unit as instantly claimed. This is evident from the fact that Tay discloses unreacted tresyl chloride in the activation step. This according to the applicants would leave some unreacted OH groups on the polyvinyl alcohol that would not bind to the heparin and hence would not give a polymer with heparin attached to the carbon in every repeating unit.

Tay et al use an analogous procedure reported by Nilsson et al (Biochemical and Biophysical Research Communication, 1981, 102(1), 449-457). Nilsson discloses that in the activation of related polymers the activation of the OH groups with tresyl chloride a high amount of tresyl groups (> 1 mmol/g dry product) were obtained after only 10 minutes of reaction (page 452, lines 3-5 under the subtitle- Activation) even with a low amount tresyl chloride used. This same procedure is used by Tay. Since the polyvinyl alcohol used by Tay has only one OH group per repeat unit of the polymer, all the OH groups will be activated. The unreacted tresyl chloride in Tay's is excess that is removed. Hence the subsequent coupling of the activated polyvinyl alcohol with heparin would lead to a heparin in every repeat unit in the structural formula recited in instant claim 1. The polymer used by Tay is polyvinyl alcohol in which the polymer main chain is a vinyl polymer (meets limitation of claim 11). Applicants further argue that Tay does not expressly disclose that the carbohydrate chain W includes a structure corresponding to at least a portion of the basic structure having an average of at least one sulfate group. Tay uses heparin with an average molecular weight of 6300 (page 13, left column, first paragraph). With an average molecular weight of 540 per repeat unit, the number of repeat units in Tay's heparin is 12. This meets the limitation of W being a carbohydrate with a structure corresponding to at least a portion of a glycosaminoglycan. One of ordinary skill in the art also knows that heparin is a sulfated glycosaminoglycan and has at least one sulfate group per repeat unit. These disclosures of Tay meets the limitations of the structural features and the number of units (2-50) recited for W in instant claim 1.

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Applicants argue that Larsson discloses a polymer having functional groups distributed along the backbone and having various bound glycosaminoglycans distributed along the backbone does not necessarily result in a glycosaminoglycan in each and every monomeric unit.

Larsson meets the limitations of instant claim 1. Instant claim 1 recites that n (the number of repeating units) is at least one. Larsson's polymer (polyallylamine) which has heparin distributed on the backbone has a heparin (a carbohydrate with at least a portion comprising the basic structure of a glycosaminoglycan) in at least one repeat ($n = 1$) unit of the polymer.

Regarding claims 2 and 8 applicants argue that patentable weight must be given to at least the identity of the functional group formed by the decomposition and its bond to the polymer chain. The instant claims are not drawn to an identity as to the functional group formed by the decomposition and its bond to the polymer main chain. The functional group of the glycosaminoglycan and its bonding to the main chain of the polymer of Larsson and Tay read on instant claims 2 and 8.

Claim 6 is drawn to a functionalized polymer in accordance with any one of claims 1-3. The recitation that it is a cell growth agent is intended use and not given patentable weight. Since Tay and Larsson's functionalized polymers meet the limitations of instant claims 1-3, the limitations of claim 6 is also met.

Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Joh (US 4415490).

Claim 12 is drawn to a functionalized polymer according to claim 1 wherein the polymer main chain is hydrophobic and the carbohydrate chain attached to the polymer main chain is hydrophilic.

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Joh drawn to non-thrombogenic materials, teaches a material comprising a base polymer covalently bonded to heparin at each bonding site between the heparin and base polymer. The carbohydrate part of the material is a partly decomposed heparin (a heparinate) molecule bonded to a vinyl chloride-ethylene-vinyl alcohol copolymer (col. 14, example 10). Since the polymer was washed and then bonded to heparinate the polymer is hydrophobic. Since an aqueous solution of sodium heparinate used in making this functionalized polymer the carbohydrate part is hydrophilic. This disclosure is seen to meet the limitations of instant claim 12.

Conclusion

Claims 1-3 and 6-12 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

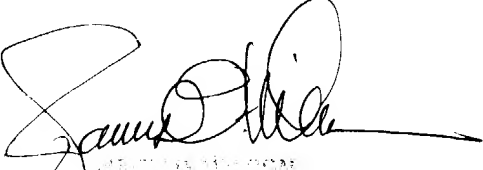
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK



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